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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/490,345 01/24/00 LUEDTKE

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PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON IA 50131

 EXAMINER

MEHTA, A

| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED:

08/01/01

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|-----------------|----------------|
| | 09/490,345 | LUEDTKE ET AL. |
| Examiner | Art Unit | |
| Ashwin Mehta | 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____ .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-49 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

**KATRINA TURNER
PATENT ANALYST**

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____ .
16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . 20) Other: _____ .

DETAILED ACTION

Claim Objections

1. Claims 1, 6, 21, 25, 37, and 40 are objected to for the inclusion of a blank line where the ATCC accession number should be. Inclusion of the number will overcome the objection.
2. Claims 8 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 8 has been examined as if "the inbred maize plant of claim 2" referred to the plant produced by growing the seed of PH3PG, and claim 27 has been examined as if "the inbred maize plant of claim 21" referred to a maize plant having all of the physiological and morphological characteristics of inbred line PH3PG.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-17 and 21-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,188,001 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both appear to be drawn to the same maize inbred line. The instantly claimed inbred line and that of 6,188,001 (PH1W0) share numerous traits, or differ due to minor morphological variations that would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH3PG. Further, the designation "PH3PG" does not distinguish the instantly claimed seeds and plants from PH1W0, as this appears to be an arbitrarily assigned designation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they require the plants of the claim from which they depend to be male sterile. However, the plants recited in claims 2 and 20, namely plants having all of the morphological and physiological characteristics of the deposited line, aren't defined in the specification as being male sterile. Page 20, lines 32-33, indicates that the cytoplasm or other factors of the inbred can be routinely manipulated to make a male-sterile form. However, this would be a characteristic that is not possessed by the deposited line, thereby making it a different line. Further, claims 3 and 22 do not indicate that the plant was at all manipulated to become

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male sterile, but rather that it was only grown from seed of line PH3PG. It is therefore not clear whether claims 3 and 22 are directed towards PH3PG, or another plant.

5. Claims 4, 5, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they fail to specify which characteristics are present in the tissue culture, and so fail to adequately characterize the tissue culture. Amending claims 4 and 23 to indicate that the tissue culture regenerates plants having all of the physiological and morphological characteristics of maize inbred line PH3PG would overcome the rejection.

6. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations "maize inbred line designated PH3PG" in line 1 of claim 1, "inbred line PH3PG" in line 2 of claims 6, 21, 25, and line 1 of claim 37, and "inbred maize line PH3PG" in line 2 of claim 40 render the claims and those dependent thereon indefinite. Since the name "PH3PG" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics which are associated with that denomination. The name "PH3PG" does not clearly identify the claimed hybrid maize seed, and does not set forth the metes and bounds of the claimed invention. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no claimed description of the maize plant that encompasses all of its traits. Amending claims 1, 6, 21, 25, 37, and 40 to recite the ATCC deposit number in which seed of maize inbred line PH3PG has been deposited would overcome the rejection.

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7. Claims 6 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "capable of expressing" in lines 1-2 of claims 6 and 25 renders them indefinite. The recitation does not make clear whether or not the characteristics are expressed. It is suggested that "capable of" be deleted from the claims.

8. Claims 5 and 24 recite the limitation "or protoplasts" in line 1. There is insufficient antecedent basis for this limitation in the claim or the claim from which it depends. It is suggested that the recitation "the cells or protoplasts being" in line 1 be replaced with --wherein cells or protoplasts are derived--.

9. Claims 14, 33, 41, 45, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they do not indicate the "standards" against which the listed traits should be compared to determine the resistance to root lodging, resistance to stalk lodging, yield, etc. The claimed plants only have two of the characteristics of PH3PG. It is not clear what type of plants the claimed plants should be compared to, in order to determine the characteristics listed in the claim. In addition, the recitations of "good", "early", "low", "high", and "above average" are unduly narrative, and when not associated with a specific numerical value, have no art-recognized meaning. Further still, the recitation "Northcentral region of the United States" is also indefinite, since the specification does not define the states that make up

this region. It is therefore not clear how one would determine if the claimed plant is particularly suited to it.

10. Claims 15-17 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 34 are drawn to a method for developing a maize plant in a plant breeding program, and the claims indicate that the indicated maize plant, or its parts, would be used as a source of breeding material. However, the claims are indefinite because they do not set forth any specific method steps with regard to how the maize plant or parts would be developed. All that is indicated is that it would be used.

11. Claims 16 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they refer to the maize breeding program of the claim from which they depend, whereas those claims are drawn to a method for developing a maize plant.

12. Claims 17, 36, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in that it is unclear what would constitute the maize plants and parts, given that they are the products of multiple crosses and it is unclear what characteristics said plants and plant parts would have. With regard to claims 17 and 36, it remains unclear how

many generations would be encompassed by the breeding program of the claim from which they depend.

13. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis for the recitation "A further derived maize plant" in the claim or the claim from which it depends. It is suggested that the recitation be replaced with --A PH3PG-derived maize plant--.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-49 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants intend to deposit seeds for PH3PG at the ATCC, but there is no indication that the

seeds have been deposited. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-17 and 21-46 are rejected under 35 U.S.C. § 102 (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over Piper (U.S. Patent No. 6,188,001 B1).

The claims broadly encompass a plant, or parts thereof, having characteristics of maize inbred line PH3PG, seed or progeny derived from maize plant PH3PG, maize plants derived from PH3PG, tissue culture derived from PH3PG, methods of using said plant in a breeding program; methods to producing PH3PG plants comprising one or more transgenes.

Piper teaches seed of maize inbred line PH1W0, plants produced by growing said seed, and plants and plant parts having all of the physiological and morphological characteristics of inbred line PH1W0. It appears that the claimed plants and seeds of the instant invention may be the same as PH1W0, given that each has a light green glume color, buff dry husk color, have a pink anther color, high yields, and are adapted to the Northcentral region of the United States, for example (Table 1; col. 10, lines 50-62). Alternatively, if the claimed plants, plant parts, and seeds of PH3PG are not identical to PH1W0, then it appears that PH1W0 only differs from the

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claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH3PG. Piper also teaches production of tissue culture of regenerable cells from a plant of line PH1W0, a plant produced from tissue culture of PH1W0, methods for producing hybrid plants wherein a plant of inbred line PH1W0 is crossed with itself or another maize plant, maize plant pedigree breeding, and production of male sterile forms of the inbred (col. 1, line 56 to col. 3, line 39; col. 15, line 51 to col. 14, line 18). Piper also teaches a method for producing inbred PH1W0, comprising planting a collection of seeds comprising seed of a hybrid, one of whose parents is PH1W0, and wherein the collection also comprises seed of PH1W0, growing the plants and selecting the inbred PH1W0 plants based on its decreased vigor, or by their genotype (col. 3, line 40 to col. 4, line 36). Introduction of other genes into PH1W0 via genetic engineering or breeding is also taught, as well as crossing the transformed plant with another plant to produce progeny comprising the inherited transgene (col. 16, line 27 to col. 24, line 67). As cultivar PH1W0 is the same as cultivar PH3PG, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Piper. Amending claims 1, 6, 21, 25, 37, and 40 to include the ATCC accession number will overcome the rejection for claims 1-13, 15-17, 21-32, 34-40, and 42-44.

However, even with the inclusion of the ATCC number, the plants of claims 14, 33, 41, 45, and 46 are still taught by Piper, as inbred line PH1W0 has at least two of the characteristics of PH3PG listed in those claims. The process of making the claimed plants does not distinguish the plants themselves from those taught by the reference. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art, if not anticipated by Piper.

16. No claims are allowed.

CLOSING REMARKS

Any inquiry concerning this communication should be directed to Examiner Ashwin Mehta, whose telephone number is (703) 306-4540. The Examiner can normally be reached Monday-Friday, from 8:30 A.M. - 5:00 P.M. The fax phone number for the group is (703) 305-3014. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

Ashwin D. Mehta
06/29/01